07 431 533

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/431,533	11/03/89	MORTON	D P312462

SILBERBERG EXAMINER

18N1/1227

DAVID L. PARKER, ESQ.
ARNOLD, WHITE AND DURKEE
P.O. BOX 4433
HOUSTON, TEXAS 77210

ART UNIT	PAPER NUMBER
1802	41

DATE MAILED: 12/27/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on _____ ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 2-5, 7-10, 19-58, 62-65 are pending in the application.
   Of the above, claims 2-5, 7-10, 20-58 are withdrawn from consideration.
2. ☒ Claims 1, 6, 11-18, 55-61 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 19, 62-65 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges the response filed 9/21/95 amending the claims and adding claim 62.

Claims 1, 6, 11-18, 55-61 have been cancelled.

Claims 2-5, 7-10, 19-58 and 62-64 are pending in the application.

Claims 2-5, 7-10, 20-58, have been withdrawn from consideration. Claims 19, 62-65 are under examination.

(a) The rejection of claim 19 under 35 U.S.C. § 112, second paragraph, as being indefinite is obviated by the amendment to the claim.

Applicant's arguments filed 9/21/95, have been fully and carefully considered but they are not deemed to be persuasive.

(1) The objection to and the rejection of claim 19 and now 65 under 35 U.S.C. § 112, first paragraph, regarding the issue of "enhancing the production of antibodies" is maintained.

The Examiner has considered Dr. Gupta assertion regarding "the feasibility of "enhancement" of antibody produced in human subjects. Applicants have submitted a graph showing increased antibody titers of melanoma patients administered UTAA "in the form of irradiated melanoma cells." Applicants claims are directed to a "substantially purified tumor antigen", not melanoma cells which have UTAA antigen on them. The use of melanoma cells having UTAA antigen on them, does not support a claim to the substantially purified antigen enhancing the production of anti-UTAA antibodies over those preexisting in melanoma patients.

(2) The rejection of claims 19 and 62 under 35 U.S.C. § 102(b) as being anticipated by Real et al is maintained

The Examiner has considered the Table submitted in the response. However, none of the asserted properties listed in the Table are found in the claims. Applicant cannot rely on limitations not recited in the claims to distinguish over the prior art.

(3) The rejection of claims 62-64 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as

obvious over Paulie et al or Euhus et al is maintained.

The Examiner has considered the Declaration of Dr. Gupta submitted to establish the differences between the claimed protein and that of the prior art (Paulie et al).

The declaration is insufficient for the following:

(a) Dr. Gupta indicates that two monoclonal antibodies obtained from Dr. Paulie were evaluated (7E9 and P7A5).

Consideration can only be given to evidence obtained using Ab 7E9, as this is at least one of the monoclonals described by Paulie et al. There are no details set forth which address the source of monoclonal P7A5, which is indicated to be the result of "another fusion".

(b) Dr. Gupta indicates that "two batches of UTAA 90 kd subunit were prepared". The preparation of these "batches" of UTAA antigen is not set forth, or indicated to be that which is set forth in the disclosure.

(c) Dr. Gupta has used a monoclonal C6 in evaluation of the UTAA antigen. Note the Western Blot shows the use of monoclonal C6 to detect the claimed UTAA antigen. The source of this monoclonal is not set forth and monoclonal C6 is not disclosed in the specification. Therefore, the immunological relationship between C6 and the UTAA antigen has not been established.

(d) There are no molecular standards depicted on figure 1 and those shown on figures 2 and 3 are not identified.

Therefore, the submitted evidence is not sufficient to establish that the antigen of Paulie et al is not the same as that claimed.

And if the prior art antigen is not the same as that claimed, it is an obvious variation of that claimed, which the teachings of the prior art reference(s) would have reasonably suggested to one of ordinary skill in the art at the time the invention was made, the isolation of the antigen, making the claimed invention as a whole prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made.

Regarding the rejection over Euhus et al, Applicant urges that

the disclosure of Euhus et al "provides a crudely purified form of UTAA." Applicant further contends that the prior art disclosure "must teach how to make and use" and "sufficiently describe the claimed invention to have placed [it] in the public possession".

Euhus et al discloses a protein having a molecular weight of 111 kd, identified as UTAA. Euhus et al indicates that the UTAA was obtained from melanoma cells. Euhus et al describe methods of obtaining the UTAA antigen, and indicate that UTAA was recovered using anion exchange chromatograph. Euhus et al teach, that after SDS-PAGE separated into 142 kd and 111 kd. Thus, Euhus et al teach a source of the antigen, and methods which a person of skill in the art would use to obtain the antigen. Applicant has provided no evidence why a person of skill in the art with the disclosure of Euhus et al in hand could not obtain a substantially purified UTAA antigen within the scope of the claims.

The UTAA of Euhus et al appears to be substantially purified as of the claims. As the separated fractions are comprised of a 142 kd and a 111 kd fraction, in the absence of evidence the UTAA appears to comprise at least .6% of the total protein and be further purified, as Euhus et al does not indicate the presence of any other protein(s).

And if the prior art antigen is not the same, it is an obvious variant, which would function in an equivalent manner. It is the Examiner's position that the teachings of the prior art suggest the isolation of a "substantially purified UTAA antigen" within the range claimed.

Obviousness does not require absolute predictability (see In re Lamberti 192 USPQ 278; in re Miegel et al. 159 USPQ 716; in re Moreton 129 USPQ 288) but only a reasonable expectation of success (see In re Longi 225 USPQ 645; In re Pantzer et al. 144 USPQ 415; and IN re Farnham et al. 188 USPQ 365.

(3) The rejection of claim 19 is under 35 U.S.C. § 103 as being unpatentable over Euhus et al is maintained.

Euhus et al teach the antigen and indicate that a monoclonal antibody has been made to the antigen.

Although the prior art does not specifically indicate

"administration of the UTAA antigen", Euhus et al teachings suggest the "giving" of the UTAA antigen to a host to at least raise monoclonal antibodies. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to "administer" UTAA for the purpose of obtaining a source of antibody which would be useful in assay.

The following is a new grounds of rejection.

Claims 19 and 65 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 65 appear to be duplicative. "More than one claim may be presented provided they differ substantially for each other. Both claims comprise "administering an effective amount of the antigen composition of claim 62". Applicants remarks have not served to establish that claims 19 and 65 differ.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure, failing to teach how to make and/or use the invention.

Applicants have presented claim 65 which recites "enhancing antibody". The specification fails to demonstrate that the administration of substantially purified UTAA will result in enhancement of antibody to UTAA.

The specification fails to define or describe amounts of the antigen which would result in an "enhanced" production of antibody

as opposed to "inducing" antibody.

Claims 62 and 65 rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1802.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. Sidberry whose telephone number is (703) 308-0170.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sidberry/hfs
5 December 21, 1995

HAZEL F. SIDBERRY
PRIMARY EXAMINER
GROUP 1800